PATENT
672601-2001

REMARKS

The November 23, 2005 Office Action required restriction under 35 U.S.C. 121 from among the following four groups.

I. Claims 1-9 and 28-36 drawn to a method of treating allergy, classified in class 424, subclass 275.1;

II. Claims 10-23, 28-36 and 42 drawn to a method of treating infection, classified in class 424, subclass 260.1;

III. Claims 24-36 and 43 drawn to a method of treating a condition in a patient in need thereof, wherein the condition is treatable by up-regulation of the activity of NK cells, classified in class 424, subclass 277.1;

IV. Claims 37-41 drawn to a chitin composition and delivery device, classified in class 435, subclass 810.

The Office Action also required election of a specific allergen from claims 2-6 of Group I; and a specific pathogen from the claims of Group II.

For the purpose of examination, Applicants hereby elect Group I and the species "aeroallergens" **with traverse**. However, Applicants respectfully request that the restriction requirement and the requirement for election of species be reconsidered and withdrawn in view of the remarks herein.

The MPEP lists two criteria for a proper restriction requirement. First, the inventions must be independent or distinct. MPEP § 803. Second, searching the additional invention must constitute an undue burden on the examiner. *Id.* The MPEP states that *"if the search and examination of all the claims in an application can be made without serious burden, the examiner **must** examine them on the merits, even though they include claims to independent or distinct inventions."* *Id.* (Emphasis added).

It is respectfully submitted that the claims of Groups I-IV are not independent or distinct as the claims of all Groups relate to chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation. Furthermore, it is respectfully submitted that a search and examination of the claims of Groups I-IV can easily be performed without serious burden. Because the claims of Groups I-IV all involve chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation, it is inevitable that a search and examination of the claims of Groups I-IV will be co-extensive and will require a review of the same art. The fact that the International Searching Authority and the International Preliminary Examining Authority were able to perform a search and examination

of all the claims of the present application together, without breaking the claims up into separate groups and/or requiring the payment of additional fees for search and examination, provides compelling evidence that such a search and examination of all of the claims of the present application can readily be performed without undue burden. Accordingly, the Examiner **must** examine all of the claims together. Performing a separate search and examination of the claims of Groups I-IV would be repetitive and inefficient, and would result in severe prejudice to the Applicant, both in terms of expense and time, particularly in view of GATT, whereby a shortened patent term may result in any divisional applications filed.

Furthermore, the present Office Action fails to make a proper requirement for restriction under 35 U.S.C. 121 or 37 CFR 1.141-1.146. The MPEP states that the *"examiner must provide reasons and/or examples to support conclusions"* when making a requirement for restriction, and that *"for purposes of the initial requirement, a serious burden on the examiner may be prima facie shown by appropriate explanation of separate classification, or separate status in the art, or a different field of search as defined in MPEP § 808.02"*. MPEP §803. The Office Action fails to provide any reasoning or evidence to show that the claims of Groups I-IV constitute inventions that are independent or distinct, and also fails to provide any reasoning or evidence to show that searching the claims of each of Groups I-IV would constitute an undue burden. Consequently, the Office Action can not be used to require restriction under 35 U.S.C. 121.

In summary, the requirement for restriction has not been shown to be proper, especially since the claims of each of Groups I-IV contain the "special technical feature" of chitin microparticles having an average diameter of less than 10μm administered intranasally or by inhalation, and the claims of each of Groups I-IV also represent subject matter that is interrelated and not distinct, and finally also because the requisite showing of serious burden in examining all of the claims has not been made, and the fact that the International Searching Authority and the International Preliminary Examining Authority have already been able to conduct such a search and examination provides compelling evidence that such a search and examination can be made without undue burden. Consequently, reconsideration and withdrawal of the restriction requirement is respectfully requested.

The Office Acton asserts that a species of allergen must be elected if the claims of Group I are elected and a species of pathogen must be elected if the claims of Group II are elected. As

stated above, Applicants hereby elect the species "aeroallergens" from within Group I, with traverse.

The requirement for an election of species is not proper. M.P.E.P. § 808.01(a) states that *"where there is no disclosure of relationship between species (see M.P.E.P. §806.04 (b)), they are independent inventions and election of one invention is required"*. However, even where there is no disclosure of relationship between species, 37 CFR 1.141 provides that a reasonable number of species may still be claimed in one application if the other conditions of the rule are met.

It is respectfully submitted that there is a disclosed relationship between the species of allergens and pathogens recited in the claims since the specification and claims disclose that they are all treatable using the chitin microparticles of the present invention when administered intranasally or by inhalation. Furthermore, Applicants submit that the number of species is sufficiently few that a search and examination of all species can be performed without undue burden. This is especially true because the search and examination of each species will likely be co-extensive and, in any event, will involve such interrelated art in the very narrow field of using chitin microparticles in medical treatments, that search and examination of the all of the species can be readily performed at the same time. Furthermore, the fact that the International Searching Authority and the International Preliminary Examining Authority were able to perform a search and examination including all of the species simultaneously provides compelling evidence that such a search and examination can readily be performed without undue burden.

In summary, the requirement for an election of species has not been shown to be proper, especially because there is a disclosed relationship between all of the species claimed and the number of species is sufficiently few that a search and examination of all species can readily be performed, as demonstrated by the fact that the International Searching Authority and the International Preliminary Examining Authority have already been able to conduct such a search and examination. Consequently, reconsideration and withdrawal of the requirement for an election of species is respectfully requested.

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CONCLUSION

Reconsideration and withdrawal of the restriction and election of species requirements, and favorable examination on the merits, are respectfully requested.

Respectfully submitted,
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